Syllabus

# HILLSBOROUGH COUNTY, FLORIDA, ET AL. *v.* AUTOMATED MEDICAL LABORATORIES, INC.

## APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 83–1925. Argued April 16, 1985—Decided June 3, 1985

In 1980, appellant Hillsborough County adopted ordinances and promulgated implementing regulations governing blood plasma centers within the county. One ordinance requires that blood donors be tested for hepatitis, that they donate at only one center, and that they be given a breath-analysis test for alcohol content before each donation. Pursuant to § 351 of the Public Health Service Act, the Food and Drug Administration (FDA) has promulgated federal regulations establishing minimum standards for the collection of blood plasma. Appellee operator of a blood plasma center located in appellant county filed suit in Federal District Court, challenging the constitutionality of the ordinances and implementing regulations on the ground, *inter alia*, that they violated the Supremacy Clause, and seeking declaratory and injunctive relief. The District Court upheld the ordinances and regulations, except the requirement that the donor be subject to a breath-analysis test. The Court of Appeals affirmed in part and reversed in part, holding that the FDA's regulations pre-empted all provisions of the ordinances and implementing regulations.

*Held:* Appellant county's ordinances and implementing regulations are not pre-empted by the federal regulations. Pp. 712–723.

(a) No intent to pre-empt may be inferred from the comprehensiveness of the federal regulations. While the regulations when issued in 1973 covered only plasma to be used in injections, the FDA has not indicated that regulations issued since that time expanding coverage to other uses have affected its express disavowal in 1973 of any intent to pre-empt state and local regulation, and such expansion of coverage does not cast doubt on the continued validity of that disavowal. Even in the absence of the disavowal, the comprehensiveness of the FDA's regulations would not justify pre-emption. To infer pre-emption whenever a federal agency deals with a problem comprehensively would be tantamount to saying that whenever the agency decides to step into a field, its regulations will be exclusive. Such a rule would be inconsistent with the federal-state balance embodied in this Court's Supremacy Clause jurisprudence. The adoption of the National Blood Policy in 1974, which

sets forth a broad statement of goals with respect to blood collection and distribution and calls for cooperation between the Federal Government and the private sector, does not support the claim that the federal regulations have grown so comprehensive since 1973 as to justify the inference of complete pre-emption. Pp. 716–719.

(b) Nor can an intent to pre-empt be inferred from the purported dominant federal interest in the field of blood plasma regulation. The factors indicating federal dominance are absent here. The regulation of health and safety matters is primarily and historically a matter of local concern, and the National Blood Policy is not a sufficient indication of federal dominance. Pp. 719–720.

(c) Any concern that the challenged ordinances impose on plasma centers and donors requirements more stringent than those imposed by the federal regulations and therefore present a serious obstacle to the federal goal of ensuring an "adequate supply of plasma" is too speculative to support pre-emption. The District Court's findings rejecting appellee's factual assertions with respect to this concern, the lack of evidence of a threat to the "adequacy" of the plasma supply, and the lack of any statement by the FDA on the subject of "adequacy," all lead to the conclusion that appellant county's requirements do not imperil the federal goal. And where the record does not indicate that appellee has received the necessary federal exemption from the good-health requirement needed to collect plasma from individuals with hepatitis, appellee lacks standing to challenge the ordinances on the ground that they conflict with the federal regulations because they prevent individuals with hepatitis from donating their plasma. Pp. 720–722.

722 F. 2d 1526, reversed and remanded.

MARSHALL, J., delivered the opinion for a unanimous Court.

*Emeline C. Acton* argued the cause for appellants. With her on the briefs was *Joe Horn Mount.*

*Paul J. Larkin, Jr.*, argued the cause *pro hac vice* for the United States as *amicus curiae* urging reversal. With him on the brief were *Solicitor General Lee, Acting Assistant Attorney General Willard, Deputy Solicitor General Geller,* and *Margaret E. Clark.*

*Larry A. Stumpf* argued the cause for appellee. With him on the brief was *Victoria L. Baden.*

*Richard Landfield* argued the cause for the American Blood Resources Association et al. as *amici curiae* urging affirmance. With him on the brief was *William W. Becker.**

JUSTICE MARSHALL delivered the opinion of the Court.

The question presented is whether the federal regulations governing the collection of blood plasma from paid donors pre-empt certain local ordinances.

I

Appellee Automated Medical Laboratories, Inc., is a Florida corporation that operates, through subsidiaries, eight blood plasma centers in the United States. One of the centers, Tampa Plasma Corporation (TPC), is located in Hillsborough County, Florida. Appellee's plasma centers collect blood plasma from donors by employing a procedure called plasmapheresis. Under this procedure, whole blood removed from the donor is separated into plasma and other components, and "at least the red blood cells are returned to the donor," 21 CFR §606.3(e) (1984). Appellee sells the plasma to pharmaceutical manufacturers.

Vendors of blood products, such as TPC, are subject to federal supervision. Under §351(a) of the Public Health Service Act, 58 Stat. 702, as amended, 42 U. S. C. §262(a), such vendors must be licensed by the Secretary of Health and Human Services (HHS). Licenses are issued only on a showing that the vendor's establishment and blood products meet certain safety, purity, and potency standards established by the Secretary. 42 U. S. C. §262(d). HHS is authorized to inspect such establishments for compliance. §262(c).

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**Benjamin W. Heineman, Jr.*, filed a brief for the National Association of Counties et al. as *amici curiae* urging reversal.

Briefs of *amici curiae* urging affirmance were filed for the American Blood Commission by *Michael H. Cardozo;* and for Grocery Manufacturers of America, Inc., by *Peter Barton Hutt.*

Pursuant to § 351 of the Act, the Food and Drug Administration (FDA), as the designee of the Secretary, has established standards for the collection of plasma. 21 CFR §§ 640.60–640.76 (1984). The regulations require that a licensed physician determine the suitability of a donor before the first donation and thereafter at subsequent intervals of no longer than one year. § 640.63(b)(1). A physician must also inform the donor of the hazards of the procedure and obtain the donor's consent, § 640.61, and must be on the premises when the procedure is performed, § 640.62. In addition, the regulations establish minimum standards for donor eligibility, §§ 640.63(c)–(d), specify procedures that must be followed in performing plasmapheresis, § 640.65, and impose labeling requirements, § 640.70.

In 1980, Hillsborough County adopted Ordinances 80–11 and 80–12. Ordinance 80–11 imposes a $225 license fee on plasmapheresis centers within the county. It also requires such centers to allow the County Health Department "reasonable and continuing access" to their premises for inspection purposes, and to furnish information deemed relevant by the Department. See App. 21–23.

Ordinance 80–12 establishes a countywide identification system, which requires all potential donors to obtain from the County Health Department an identification card, valid for six months, that may be used only at the plasmapheresis center specified on the card. The ordinance incorporates by reference the FDA's blood plasma regulations, but also imposes donor testing and recordkeeping requirements beyond those contained in the federal regulations. Specifically, the ordinance requires that donors be tested for hepatitis prior to registration, that they donate at only one center, and that they be given a breath analysis for alcohol content before each plasma donation. See *id.*, at 24–31.

The county has promulgated regulations to implement Ordinance 80–12. The regulations set the fee for the issuance of an identification card to a blood donor at $2. They also

establish that plasma centers must pay the county a fee of $1 for each plasmapheresis procedure performed. See *id.*, at 32–34.

In December 1981, appellee filed suit in the United States District Court for the Middle District of Florida, challenging the constitutionality of the ordinances and their implementing regulations. Appellee argued primarily that the ordinances violated the Supremacy Clause, the Commerce Clause, and the Fourteenth Amendment's Equal Protection Clause. Appellee sought a declaration that the ordinances were unlawful and a permanent injunction against their enforcement. *Id.*, at 5–20.

In November 1982, following a bench trial, the District Court upheld all portions of the local ordinances and regulations except the requirement that donors be subject to a breath-analysis test. *Id.*, at 40–46. The court rejected the Supremacy Clause challenge, discerning no evidence of federal intent to pre-empt the whole field of plasmapheresis regulation and finding no conflict between the Hillsborough County ordinances and the federal regulations.

In addition, the District Court rejected the claim that the ordinances violate the Equal Protection Clause because they regulate only centers that pay donors for plasma, and not centers in which volunteers donate whole blood. The court identified a rational basis for the distinction: paid donors sell plasma more frequently than volunteers donate whole blood, and paid donors have a higher rate of hepatitis than do volunteer donors.

Finally, the District Court found that, with one exception, the ordinances do not impermissibly burden interstate commerce. It concluded that the breath-analysis requirement would impose a large burden on plasma centers by forcing them to purchase fairly expensive testing equipment, and was not shown to achieve any purpose not adequately served by the subjective evaluations of sobriety already required by the federal regulations.

Automated Medical Laboratories appealed to the Court of Appeals for the Eleventh Circuit, which affirmed in part and reversed in part. 722 F. 2d 1526 (1984). The Court of Appeals held that the FDA's blood plasma regulations pre-empt all provisions of the county's ordinances and regulations. The court acknowledged the absence of an express indication of congressional intent to pre-empt. Relying on the pervasiveness of the FDA's regulations and on the dominance of the federal interest in plasma regulation, however, it found an implicit intent to pre-empt state and local laws on that subject. In addition, the court found a serious danger of conflict between the FDA regulations and the Hillsborough County ordinances, reasoning that "[i]f the County scheme remains in effect, the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors will be adversely affected." *Id.*, at 1533.

The Court of Appeals thus affirmed, albeit on other grounds, the District Court's invalidation of the breath-analysis requirement. It reversed the District Court's judgment upholding the remaining requirements of the Hillsborough County ordinances and regulations. In view of its decision, the court did not reach the Commerce Clause and Equal Protection challenges to the county's scheme. *Ibid.*

Hillsborough County and the County Health Department appealed to this Court pursuant to 28 U. S. C. § 1254(2).[1] We noted probable jurisdiction, 469 U. S. 1156 (1984), and we now reverse.

## II

It is a familiar and well-established principle that the Supremacy Clause, U. S. Const., Art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons* v. *Ogden*, 9 Wheat. 1, 211 (1824) (Marshall,

[1] For the purposes of § 1254(2), local ordinances are treated in the same manner as state statutes. See, *e. g.*, *New Orleans* v. *Dukes*, 427 U. S. 297, 301 (1976) *(per curiam)*; *Doran* v. *Salem Inn, Inc.*, 422 U. S. 922, 927, n. 2 (1975).

C. J.). Under the Supremacy Clause, federal law may supersede state law in several different ways. First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms. *Jones* v. *Rath Packing Co.*, 430 U. S. 519, 525 (1977). In the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation. *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947). Pre-emption of a whole field also will be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Ibid.*; see *Hines* v. *Davidowitz*, 312 U. S. 52 (1941).

Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U. S. 132, 142–143 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, *supra*, at 67. See generally *Capital Cities Cable, Inc.* v. *Crisp*, 467 U. S. 691, 698–699 (1984).

We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes. See, *e. g.*, *Capital Cities Cable, Inc.* v. *Crisp*, *supra*, at 699; *Fidelity Federal Savings & Loan Assn.* v. *De la Cuesta*, 458 U. S. 141, 153–154 (1982); *United States* v. *Shimer*, 367 U. S. 374, 381–383 (1961). Also, for the purposes of the Supremacy Clause, the constitutionality of local ordinances is analyzed in the same way as that of statewide laws. See, *e. g.*, *City of Burbank* v. *Lockheed Air Terminal, Inc.*, 411 U. S. 624 (1973).

## III

In arguing that the Hillsborough County ordinances and regulations are pre-empted, appellee faces an uphill battle. The first hurdle that appellee must overcome is the FDA's statement, when it promulgated the plasmapheresis regulations in 1973, that it did not intend its regulations to be exclusive. In response to comments expressing concern that the regulations governing the licensing of plasmapheresis facilities "would pre-empt State and local laws governing plasmapheresis," the FDA explained in a statement accompanying the regulations that "[t]hese regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities." 38 Fed. Reg. 19365 (1973).

The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme. See *supra*, at 712–713. In this case, appellee concedes that neither Congress nor the FDA expressly pre-empted state and local regulation of plasmapheresis. Thus, if the county ordinances challenged here are to fail they must do so either because Congress or the FDA *implicitly* pre-empted the whole field of plasmapheresis regulation, or because particular provisions in the local ordinances conflict with the federal scheme. According to appellee, two separate factors support the inference of a federal intent to pre-empt the whole field: the pervasiveness of the FDA's regulations and the dominance of the federal interest in this area. Appellee also argues that the challenged ordinances reduce the number of plasma donors, and that this effect conflicts with the congressional goal of ensuring an adequate supply of plasma.

The FDA's statement is dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent, see *Chevron U. S. A. Inc.* v. *Natural Resources Defense*

*Council, Inc.*, 467 U. S. 837, 842–845 (1984), or subsequent developments reveal a change in that position. Given appellee's first argument for implicit pre-emption—that the comprehensiveness of the FDA's regulations evinces an intent to pre-empt—any pre-emptive effect must result from the change since 1973 in the comprehensiveness of the federal regulations.[2] To prevail on its second argument for implicit pre-emption—the dominance of the federal interest in plasmapheresis regulation—appellee must show either that this interest became more compelling since 1973, or that, in 1973, the FDA seriously underestimated the federal interest in plasmapheresis regulation.

The second obstacle in appellee's path is the presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause. Through the challenged ordinances, Hillsborough County has attempted to protect the health of its plasma donors by preventing them from donating too frequently. See Brief for Appellants 12. It also has attempted to ensure the quality of the plasma collected so as to protect, in turn, the recipients of such plasma. "Where . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States 'we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Jones* v. *Rath Packing Co.*, 430 U. S., at 525 (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S., at 230) (citations omitted). Cf. *Kassel* v. *Consolidated Freightways Corp.*, 450 U. S. 662, 670 (1981) (deference to state regulation of safety under the dormant Commerce Clause); *id.*, at 681, n. 1 (BRENNAN, J., concurring in judgment) (same); *id.*, at 691 (REHNQUIST, J., dissenting) (same). Of course, the same principles apply where, as here, the field is said to have

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[2] Appellee does not argue that pre-emption can be inferred from the comprehensiveness of the federal statutes governing plasmapheresis.

been pre-empted by an agency, acting pursuant to congressional delegation. Appellee must thus present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation.

## IV

Given the clear indication of the FDA's intention *not to pre-empt* and the deference with which we must review the challenged ordinances, we conclude that these ordinances are not pre-empted by the federal scheme.

### A

We reject the argument that an intent to pre-empt may be inferred from the comprehensiveness of the FDA's regulations at issue here. As we have pointed out, given the FDA's 1973 statement, the relevant inquiry is whether a finding of pre-emption is justified by the increase, since 1973, in the comprehensiveness of the federal regulations. Admittedly, these regulations have been broadened over the years. When they were adopted in 1973, these regulations covered only plasma to be used in injections. In 1976, the regulations were expanded to cover also plasma to be used for the manufacture of "noninjectable" products. 41 Fed. Reg. 10762 (1976). The original regulations also were amended to "clarify and strengthen the existing Source Plasma (Human) regulations in light of FDA inspectional and other regulatory experience." *Ibid.*; see also 39 Fed. Reg. 26161 (1974) (first proposing the amendments).

The FDA has not indicated that the new regulations affected its disavowal in 1973 of any intent to pre-empt state and local regulation, and the fact that the federal scheme was expanded to reach other uses of plasma does not cast doubt

on the continued validity of that disavowal.[3] Indeed, even in the absence of the 1973 statement, the comprehensiveness of the FDA's regulations would not justify pre-emption. In *New York Dept. of Social Services* v. *Dublino*, 413 U. S. 405 (1973), the Court stated that "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *Id.*, at 415. There, in upholding state work-incentive provisions against a pre-emption challenge, the Court noted that the federal provisions "had to be sufficiently comprehensive to authorize and govern programs in States which had no . . . requirements of their own as well as cooperatively in States with such requirements." *Ibid.* But merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field. See also *De Canas* v. *Bica*, 424 U. S. 351, 359–360 (1976).

We are even more reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes. As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence. See *Jones* v. *Rath Packing Co.*, 430 U. S., at 525.

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[3] Nor do the amendments to the 1973 regulations indicate that the FDA was departing from its earlier statement; most of the changes are technical and provide no basis for inferring an intent that federal regulation be exclusive.

Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt. Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.

Appellee also relies on the promulgation of the National Blood Policy by the Department of Health, Education, and Welfare (HEW), as an indication that the federal regulatory scheme is now comprehensive enough to justify complete pre-emption. See Brief for Appellee 25–26. Such reliance is misplaced.

The National Blood Policy was established in 1974 as "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems." 39 Fed. Reg. 32702 (1974). The policy contains no regulations; instead, it is a broad statement of goals and a call for cooperation between the Federal Government and the private sector:

> "These policies are intended to achieve certain goals but do not detail methods of implementation. In developing the most effective and suitable means of reaching these goals, the Secretary will involve, as appropriate, all relevant public and private sectors and Federal Government agencies in a cooperative effort to provide the best attainable blood services." *Id.*, at 32703.

The National Blood Policy indicates that federal regulation will be employed only as a last resort: "[I]f the private sector is unable to make satisfactory progress toward implementing

these policies, a legislative and/or regulatory approach would have to be considered." *Ibid.* The adoption of this policy simply does not support the claim that the federal regulations have grown so comprehensive since 1973 as to justify the inference of complete pre-emption.

B

Appellee's second argument for pre-emption of the whole field of plasmapheresis regulation is that an intent to pre-empt can be inferred from the dominant federal interest in this field. We are unpersuaded by the argument. Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law. Neither does the Supremacy Clause require us to rank congressional enactments in order of "importance" and hold that, for those at the top of the scale, federal regulation must be exclusive.

Instead, we must look for special features warranting pre-emption. Our case law provides us with clear standards to guide our inquiry in this area. For example, in the seminal case of *Hines* v. *Davidowitz*, 312 U. S. 52 (1941), the Court inferred an intent to pre-empt from the dominance of the federal interest in foreign affairs because "the supremacy of the national power in the general field of foreign affairs . . . is made clear by the Constitution," *id.*, at 62, and the regulation of that field is "intimately blended and intertwined with responsibilities of the national government," *id.*, at 66; see also *Zschernig* v. *Miller*, 389 U. S. 429, 440–441 (1968). Needless to say, those factors are absent here. Rather, as we have stated, the regulation of health and safety matters is primarily, and historically, a matter of local concern. See *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S., at 230.[4]

[4] It follows that the FDA's 1973 statement did not underestimate the federal interest in plasmapheresis regulation.

There is also no merit in appellee's reliance on the National Blood Policy as an indication of the dominance of the federal interest in this area. Nothing in that policy takes plasma regulation out of the health-and-safety category and converts it into an area of overriding national concern.

C

Appellee's final argument is that even if the regulations are not comprehensive enough and the federal interest is not dominant enough to pre-empt the entire field of plasmapheresis regulation, the Hillsborough County ordinances must be struck down because they conflict with the federal scheme. Appellee argues principally that the challenged ordinances impose on plasma centers and donors requirements more stringent than those imposed by the federal regulations, and therefore that they present a serious obstacle to the federal goal of ensuring an "adequate supply of plasma." Tr. of Oral Arg. 24; see Brief for Appellee 30; 37 Fed. Reg. 17420 (1972). We find this concern too speculative to support pre-emption.

Appellee claims that "[t]he evidence at trial indicated that enforcement of the County ordinances would result in an increase in direct costs of plasma production by $1.50 per litre, and a total increase in production costs (including direct and indirect costs) of $7 per litre of plasma, an increase of approximately 15% in the total cost of production." Brief for Appellee 30. Appellee argues that these increased financial burdens would reduce the number of plasma centers. In addition, appellee claims, the county requirements would reduce the number of donors who only occasionally sell their plasma because such donors would be deterred by the identification-card requirement. *Id.*, at 30–31.

On the basis of the record before it, the District Court rejected each of appellee's factual assertions. The District Court found that appellee's cost-of-compliance estimates "were clouded with speculation." App. 42. It also found that appellee had presented no facts to support its conclusion that "the vendor population would decrease by twenty-five

percent." *Ibid.* These findings of fact can be set aside only if they are clearly erroneous, Fed. Rule Civ. Proc. 52(a); see *Anderson* v. *Bessemer City*, 470 U. S. 564 (1985), and hence come to us with a strong presumption of validity.

More importantly, even if the Hillsborough County ordinances had, in fact, reduced the supply of plasma in that county, it would not necessarily follow that they interfere with the federal goal of maintaining an adequate supply of plasma. Undoubtedly, overly restrictive local legislation could threaten the national plasma supply. Neither Congress nor the FDA, however, has struck a particular balance between safety and quantity; as we have noted, the regulations, which contemplated additional state and local requirements, merely establish minimum safety standards. See 38 Fed. Reg. 19365 (1973); *supra*, at 710–711. Moreover, the record in this case does not indicate what supply the Federal Government considers "adequate," and we have no reason to believe that any reduction in the quantity of plasma donated would make that supply "inadequate."

Finally, the FDA possesses the authority to promulgate regulations pre-empting local legislation that imperils the supply of plasma and can do so with relative ease. See *supra*, at 713. Moreover, the agency can be expected to monitor, on a continuing basis, the effects on the federal program of local requirements. Thus, since the agency has not suggested that the county ordinances interfere with federal goals, we are reluctant in the absence of strong evidence to find a threat to the federal goal of ensuring sufficient plasma.

Our analysis would be somewhat different had Congress not delegated to the FDA the administration of the federal program. Congress, unlike an agency, normally does not follow, years after the enactment of federal legislation, the effects of external factors on the goals that the federal legislation sought to promote. Moreover, it is more difficult for Congress to make its intentions known—for example by amending a statute—than it is for an agency to amend its regulations or to otherwise indicate its position.

In summary, given the findings of the District Court, the lack of any evidence in the record of a threat to the "adequacy" of the plasma supply, and the significance that we attach to the lack of a statement by the FDA, we conclude that the Hillsborough County requirements do not imperil the federal goal of ensuring sufficient plasma.[5]

Appellee also argues that the county ordinances conflict with the federal regulations because they prevent individuals with hepatitis from donating their plasma. See *supra*, at 710. Such plasma is used for the production of hepatitis vaccines, and the federal regulations provide for its collection pursuant to special authorization and under carefully controlled conditions. 21 CFR § 610.41 (1984). To the extent that the Hillsborough County ordinances preclude individuals with hepatitis from donating their plasma, the ordinances are said to stand in the way of the accomplishment of the federal goal of combating hepatitis.

In order to collect plasma from individuals with hepatitis, however, a plasma center must obtain from the FDA, pursuant to § 640.75, an exemption from the good-health requirements of § 640.63(c). The record does not indicate that appellee has received the required exemption. As a result, appellee could not collect plasma from individuals with hepatitis even in the absence of the county ordinances. Thus, appellee lacks standing to challenge the ordinances on this ground.[6]

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[5] Two of the *amici* argue that the county ordinances interfere with the federal interest in uniform plasma standards. There is no merit to that argument. The federal interest at stake here is to ensure minimum standards, not uniform standards. Indeed, the FDA's 1973 statement makes clear that additional, nonconflicting requirements do not interfere with federal goals, and we have found no reason to doubt the continued validity of that statement. See *supra*, at 714.

[6] Since the ordinances incorporate the FDA's regulations, see *supra*, at 710, they may in fact also provide for the type of exemptions authorized by 21 CFR § 640.75 (1984). If the ordinances were interpreted that way there would be, of course, no conflict.

V

We hold that Hillsborough County Ordinances 80–11 and 80–12, and their implementing regulations, are not preempted by the scheme for federal regulation of plasmapheresis. The judgment of the Court of Appeals for the Eleventh Circuit is therefore reversed, and the case is remanded for further proceedings consistent with this opinion.

*It is so ordered.*